IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of:

Mika JOKINEN et al.

Serial Number: 09/913,643 Group Art Unit: 1618

Filed: October 19, 2001 Examiner: Fubara, Blessing M.

For: BIODEGRADABLE CERAMIC FIBRES FROM SILICA SOLS

RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Commissioner of Patents
P.O. Box 22313-1450 September 3, 2009
Alexandria, VA 22313

Sir:

In response to the Notification of Non-Compliant Appeal Brief mailed August 7, 2009, appellants request the attached "SUMMARY OF CLAIMED SUBJECT MATTER" be substituted for the original Summary of Claimed Subject Matter contained in the Appeal Brief filed November 9, 2007.

The attached "SUMMARY OF CLAIMED SUBJECT MATTER" identifies each independent claim and support thereof in the application.

It is not believed any fee is required for entry and consideration of this Response. Nevertheless, the Commissioner is

requested to charge Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

/James C. Lydon/

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Enclosure:
SUMMARY OF CLAIMED SUBJECT MATTER

SUMMARY OF CLAIMED SUBJECT MATTER

This appeal involves a rapidly-dissolving biodegradable silica fibre. Silica fibres are typically spun from a silica sol, which can be prepared by allowing a silica-alkoxide or an organically modified silicate to react with water in the presence of an acidic or basic catalyst. The functionality of the silica precursors and the degree of branching of the silica clusters formed affect the reaction and the spinnability of the resulting silica sol (Specification, page 1, lines 21-27 and page 6, lines 12-20).

Fibres can be spun from the silica sol using known techniques such as dry spinning and centrifugal spinning (page 6, line 21 to page 7, line 4), once the silica sol has reached a threshold viscosity value (Fig. 5). The silica sol is spinnable into a fibre within a certain time period rather than at a single point, and the viscosity of the sol increases during this time period. Other factors which affect silica sol viscosity include the temperature of the sol and the amount of solvent present in the sol (page 5, lines 11-14).

The inventors have unexpectedly discovered the biodegradability of silica fibers can be varied - even when using the same recipe - by adjusting or controlling the viscosity of the spinning solution (page 5, lines 6-10). Fibers which are spun in the early stages of the spinnability period degrade more slowly in simulated body fluid that fibers spun in the later stages of

spinnability. Fig. 8 shows the SiO_2 solubility of a silica fiber (FIB 1) in simulated body fluid as a function of silica sol viscosity at the starting point of the spinning process. Fiber solubility rate clearly increases as the starting viscosity increases. Compare, for example, fibers which were aged for 2 weeks after spinning. The "2 week fiber" whose starting point viscosity was 3.52 Pas has a lower solubility rate than the "2 week" fiber whose starting point viscosity was approximately 4 Pas. Similarly, the solubility rate of the 2 week fiber whose starting point viscosity was approximately 4 Pas is lower than the solubility rate of the 2 week fiber whose starting viscosity was 15 Pas.

Fibres spun from silica sols having a higher viscosity at lower temperature degrade more rapidly than the corresponding fibres spun at a higher temperature. See page 5, lines 18-24, page 11, lines 9-11, Example 5 and Table 3.

The claimed fiber has a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h. The fiber will dissolve in about 21 days at its slowest solubility rate of 0.2 wt-%/hour.

Independent claim 30 is directed to a biodegradable silica fibre spun from silica sol, a biodegradation rate of the fibre being adjusted by controlling the starting point of the spinning process by a viscosity of the silica sol wherefrom the fibre is spun, the fibre having a solubility rate in simulated body fluid of

0.2 to 20 wt-%/h (page 6, lines 5-11)[1]. The 0.2 wt-% minimum solubility limit is supported by page 15, Table 3, fiber FIB2_A, three month aging time.

Independent claim 32 is directed to a biodegradable silica fibre spun from a silica sol, a biodegradation rate of the fibre being adjusted by controlling the viscosity of the spinning sol wherefrom the fibre is spun, the fibre having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h (page 6, lines 5-11). Again, the 0.2 wt-% minimum solubility limit is supported by page 15, Table 3, fiber FIB2_A, three month aging time.

The biodegradable fibre can be used as a delivery device or pharmaceutical preparation which is implanted, injected into or mucosally attached to a human or animal. A delivery device comprises the biodegradable fibre wherein the fibre contains a biologically active agent (page 7, lines 11-13). The biologically active agent can be a medicine, a protein, a hormone, a living or dead cell, a bacteria, a virus or a part thereof (page 8, line 1 to page 9, line 2).

A pharmaceutical preparation, such as a granulate or capsule, is a preparation which comprises the delivery device of the

[1]The "m-%/h" silica fiber solubility units recited on page 6, line 10 would be recognized as an obvious typographical error by one of ordinary skill in the art, particularly in view of page 4, lines 20-22; page 4, lines 26-28; page 15, Table 3; and Figs. 8, 10 and 12.

invention and possibly additional excipients useful in pharmaceutical preparations (page 7, lines 13-15).

Dependent claim 28 relates to a method for administering a biologically active agent to a human or animal such as a mammal, wherein the method comprises implanting, injecting or mucosally attaching a delivery device, where the delivery device comprises a biodegradable fibre comprising a biologically active agent, with the fibre spun from silica sol, a biodegradation rate of the fibre being adjusted by controlling the starting point of the spinning process by a viscosity of the silica sol wherefrom the fibre is spun, the fibre having a solubility rate in simulated body fluid of 0.2 to 20 wt-%/h (page 3, lines 19-23; page 6, lines 5-11; page 7, lines 5-10; with specific support for the 0.2 wt-% minimum solubility limit provided by page 15, Table 3, fiber FIB2_A, three month aging time).